K081641

JAN 16 2009

510(k) Summary
COULTER® LIN-X Linearity Controls

10 Submitted By:

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20 Date Submitted:

June 6, 2008

30 Device Name(s):

31 Proprietary Names

COULTER® LIN-X Linearity Control

32 Classification Name

Hematology quality control mixture
(21 CFR § 864 8625)

40 Predicate Device:

Candidate(s)	Predicate	Manufacturer	Docket Number
COULTER® LIN-X Linearity Control	COULTER® LIN-C® Linearity Control (Cleared as COULTER® Linearity Controls)	Beckman Coulter, Inc	K955334 and K061064
	CBC-Line Hematology Linearity Kit (for calibration assessment only)	R&D Systems	K942822

5 0 **Description:**

COULTER LIN-X linearity controls are stabilized human blood components whose WBC, RBC, HGB, and PLT concentrations span the instrument's reportable range Results from repeated measurements for each concentration are compared to the established expected range to assess the instrument's calibration and verify the reportable range

6 0 **Intended Use:**

COULTER LIN-X linearity controls are intended to assess calibration and verify the reportable range of COULTER cellular analysis systems listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents Refer to your Product Manuals or On-line Help System

7 0 **Comparison to Predicate(s):**

COULTER LIN-X linearity controls are essentially identical to the current COULTER LIN-C linearity controls with the exception of an additional level covering an extended cellular component range, the analyzers on which it may be used and an expanded intended use for calibration assessment

8 0 **Summary of Performance Data:**

Stability, calibration assessment, value assignment and range determination studies were conducted and demonstrate acceptable performance per manufacturing specifications The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807 92

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 16 2009

Beckman Coulter, Inc
c/o Ms Nancy Nadler
Staff Regulatory Affairs Specialist
11800 SW 147th Avenue
Miami, FL 33196

Re k081641
Trade/Device Name Coulter® LIN-X Linearity Control
Regulation Number 21 CFR 864 8625
Regulation Name Hematology Quality Control Mixture
Regulatory Class Class II
Product Code JPK
Dated January 05, 2009
Received January 06, 2009

Dear Ms Nadler

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Parts 801 and 809), and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Maria M Chan

Maria M Chan, Ph D
Acting Division Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K081641

Device Name COULTER® LIN-X Linearity Control

Indications For Use COULTER LIN-X linearity controls are intended to assess calibration and verify the reportable range of COULTER cellular analysis systems listed in the TABLE OF EXPECTED RESULTS in conjunction with specific COULTER reagents Refer to your Product Manuals or On-line Help System

Prescription Use __X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K081641